June 18, 2009

0230 9 JUN 19 A9:06

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, Maryland 20852

**Citizen Petition**

Pepper Hamilton, LLP (the "***Petitioner***") submits this petition pursuant to Sections 501, 502, 510 and 513 of the Federal Food, Drug, and Cosmetic Act (the "***Act***") and 21 CFR §10.30.

Petitioner requests that the Commissioner of Food and Drugs (the "***Commissioner***") take action to protect patient safety by

1. detaining all products which are of the generic type classified as "Remote Medication Management Systems" under 21 CFR Section 880.6315 and are manufactured or sold by Concept Medical Technologies, Inc. ("*MedAssure Medication Dispensing System*"), MedSignals Corporation, a division of LIFETECHniques, Inc. ("*MedSignal Medication Management Systems*"), Rapid Patient Monitoring, LLC ("*MediSure Medication Dispensing System*"), SentiCare, Inc. ("*PillStation*"), and TabSafe Medical Services, Inc. ("*TabSafe Medication Management System*") as they are unapproved and misbranded devices within the meaning of Section 502(o) of the Act;

and

2. detaining products which are medication management devices, such as the products manufactured and sold by HealthOneMed, Inc. ("*Dispense-A-Pill*") and Philips Lifeline ("*MD.2*"), and similar medication management devices manufactured and sold in the United States by any other establishment for a determination as to whether such devices must:

(i) conform to the general controls of the Act, including the establishment registration and device listing requirements described in 21 CFR §807 Subpart B and the premarket notification requirements described in 21 CFR §807 Subpart E;

(ii) address, as determined by the Food and Drug Administration ("***FDA***"), the special controls which, when combined with the general controls of the Act, shall be sufficient to provide reasonable assurance of the safety and effectiveness of such devices in light of the specific risks to health associated with such devices; and

(iii) obtain a substantial equivalence determination from FDA prior to marketing such devices.

FDA-2009-P-0282-0001

CP

If any such determinations are made in the affirmative, the Petitioner respectfully requests that the Commissioner under its authority seize all existing models of such unapproved and misbranded Remote Medication Management Systems and medication management devices presently on the market, enjoin the parties presently manufacturing or selling such products from continuing to market such unapproved and misbranded devices, and/or enter other appropriate relief.

## A. Action Requested

The Petitioner respectfully requests:

1. that FDA detain the following devices for a determination of seizure, injunction, and/or other appropriate relief based upon: such devices being unapproved and misbranded devices within the meaning of Section 502(o) of the Act, as (i) such devices are class II devices as they are within the generic type of devices classified as "Remote Medication Management Systems" and subject to 21 CFR Section 880.6315, (ii) neither such devices nor the establishments manufacturing or selling them having been listed with the FDA, and (iii) no notice or other information respecting any of these products has been provided to FDA as required by Section 502(o) or Section 510(k) of the Act:

   a. "*MedAssure Medication Dispensing System*"

      -- manufactured by: Concept Medical Technologies, Inc.

      P.O. Box 430098
      Birmingham, AL 35243
      Telephone: 205-970-1100
      Website: www.conceptmedtech.com

   b. "*MediSure Medication Dispensing System*"

      -- manufactured by: Rapid Patient Monitoring, LLC

      1600 South 28th Street
      Philadelphia, PA 19145
      Telephone: 215-336-1766
      Website: www.rapidpatientmonitoring.com

   c. "*MedSignals Medication Management System*"

      -- manufactured by: MedSignals Corp., a division of
      LIFETECHniques, Inc.

      217 Alamo Plaza
      San Antonio, TX 78205
      Telephone: 210-222-2067
      Website: www.medsignals.com

d. "*PillStation*"

-- manufactured by: SentiCare, Inc.

132 Turnpike Road
Southborough, MA 01772
Telephone: 508-875-2401
Website: www.senticare.com

e. "*TabSafe Medication Management System*"

-- manufactured by: TabSafe Medical Services, Inc.

1050 Northfield Court - Suite 100
Roswell, GA 30076
Telephone: 678-990-8450
Website: www.tabsafe.com

2. Determine that the devices listed in Section A.1 above and all other unregistered devices manufactured and distributed for use in the United States which are composed of software, a medication delivery unit and medication packaging, and which are intended to store the patient's prescribed medications in a delivery unit, notify the patient when the prescribed medications are due to be taken, select, from the prescribed medications stored in the delivery unit, the prescribed medications to be delivered to the patient, to release the selected prescribed medications to the patient to a tray of the delivery unit accessible to the patient on the patient's command and to record a history of the event are within the generic type of device within the scope of 21 CFR 880.6315 as "Remote Medication Management Systems" and, as such, are "class II" medical devices subject to the general controls of the Act, including the establishment registration and device listing requirements described in 21 CFR §807 Subpart B and the premarket notification requirements described in 21 CFR §807 Subpart E.

3. that FDA detain the following devices for a determination of seizure, injunction, and/or other appropriate relief based upon: such devices being unapproved and misbranded devices within the meaning of Section 502(o) of the Act, as (i) neither such devices nor the establishments manufacturing or selling them having been listed with the FDA and (ii) no notice or other information respecting any of these products has been provided to FDA as required by such Section 502(o) or Section 510(k) of the Act:

a. "*Dispense-A-Pill*"

-- manufactured by: HealthOneMed, Inc.;

1550 Pond Road, Suite 102
Allentown, PA 18104
Telephone: 877-810-2888
Website: www.healthonemed.com

b. *"MD.2"*

-- manufactured by: Philips Lifeline

111 Lawrence Street
Framingham, MA 01702
Telephone: 508-988-1000
Website: www.lifelinesys.com
Product website: www.epill.com/lifelinemd2

4. (i) Determine that devices listed in Section A.3 above and all other unregistered devices manufactured and distributed for use in the United States which are composed of software, a medication delivery unit and medication packaging, and which are intended to store the patient's prescribed medications in a delivery unit, notify the patient when the prescribed medications are due to be taken, select, from the prescribed medications stored in the delivery unit, the prescribed medications to be delivered to the patient, to release the selected prescribed medications to the patient to a tray of the delivery unit accessible to the patient on the patient's command and to record a history of the event (such devices referred to hereafter as "***medication management devices***") shall be classified as "class II" medical devices subject to the general controls of the Act, including the establishment registration and device listing requirements described in 21 CFR §807 Subpart B and the premarket notification requirements described in 21 CFR §807 Subpart E.

and

(ii) Determine the special controls which shall be applicable to such medication management devices and which, when combined with the general controls of the Act, shall be sufficient to provide reasonable assurance of the safety and effectiveness of such devices.

## B. Statement of Grounds

### 1. Legal Framework

a. *FDA Classification and Regulation of Devices*

The Act defines a "device" to be:

". . . an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar related article . . .intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease . . . or intended to affect the structure or any function of the body . . . and which does not achieve any of its primary intended purposes through chemical

action within or on the body . . . and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."[1]

FDA has identified a broad range of products which are "devices" within the meaning of the Act, and which it has further determined shall be classified as class I, class II or class III, according to the relative predictability of their safety and effectiveness when used for their intended purposes. For example and relevant to this Petition, FDA has identified "daily activity assist devices" for use with a patient's medications as "devices" within the meaning of the Act, and has classified certain generic types of such devices as class I devices.[2]

b. *FDA Classification and Regulation of Devices Intended for Use as Medication Dispensers or Reminders*

21 CFR §890.5050 defines "daily activity assist devices" to include

" . . . a modified adaptor or utensil (e.g., a dressing, grooming, recreational activity, transfer, eating, or homemaking aid) that is intended for medical purposes to assist a patient to perform a specific function."[3]

FDA has further identified two generic types of devices within this category of "daily activity assist devices" which are intended to assist a patient with his or her medications:

1). "Solid Medication Dispenser" (Product Code – NXB), which is intended " . . . to issue solid (pills) medication" and which " . . . can function independently, with components or within a system"[4];

and

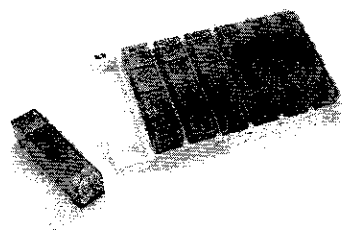
2). "Medication Reminder" (Product Code – NXQ), which is intended " . . . to provide alerts to patients or healthcare providers for pre-determined medication dosing schedules . . . " and which " . . . may incorporate wireless communication".[5]

A review of the devices listed with FDA with reference to these Product Codes establishes that the devices classified as "Solid Medication Dispensers" are typically traditional pill boxes or other simple containers which may be components of "Medication Reminders" providing visible or audible alerts when the patient should take the medications the patient had previously loaded into the Dispenser.[6]

---

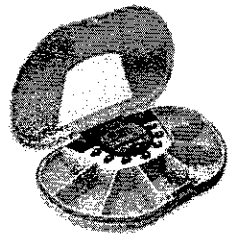
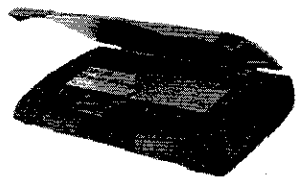
[1] 21 USC §321(h)
[2] 21 CFR §890.5050
[3] *Ibid, subsection (a)*
[4] See FDA Product Classification Database listing for Product Code NXB.
[5] See FDA Product Classification Database listing for Product Code NXQ.
[6] See "Dose Alert", Pharmaceutical Direct, Inc., www.dose-alert.com

Other devices which have not been listed with FDA clearly fall into this generic category of a simple "assist" device, such as the plastic pill box or pill organizer (pictured below).

| | |
|---|---|
| *Figure #1: Example of Solid Medication Dispenser.* |  |

These devices are typically filled by the patient or a caregiver based upon the pharmacy labels on the prescription bottle. They contain compartments which show the time of day and the day of the week when the pills are to be taken. Pills to be taken by the patient are placed into their respective compartments according to their prescribed dosing schedules.

A more current adaptation of these Solid Medication Dispensers are Medication Reminders which incorporate medication storage and dosage alerts (shown below).

| | | |
|---|---|---|
| *Figure #2: Examples of Medication Reminders* | VitaCarry Reminder System<br>www.bindependent.com |  |
| | Med-eMonitor™<br>www.informedix.com |  |

These devices are variations of the Dispenser shown in Figure #1, but they also include alarm clocks which remind the patient when to take a medication and which compartment holds that medication.

Significantly, these generic types of "daily assist" devices do not select and deliver individual medications for the patient. The patient or caregiver must manually load each compartment with the proper medications, so that these devices are merely organizers and reminders.

c. *FDA Classification and Regulation of Devices Intended for Use as Medication Management Devices*

Over the past several years, patient compliance with prescribed medication regimens has become a source of increasing concern within the pharmaceutical industry and among healthcare practitioners. Non-adherence with prescription regimens has been identified as a significant contributor to increased use of medical resources, especially by the elderly, resulting in increased hospital and nursing home admissions and substantially greater annual healthcare costs.[7]

In response to this challenge, several companies have developed products which are intended to enhance patient compliance by taking over the sorting, selection, dispensing and overall medication control functions historically performed manually in the home by the patient. As such, these products have become much more than the traditional class I "daily assist" devices designated as "Medication Dispensers" and "Medication Reminders", where many of the medication handling and management functions previously performed manually by the patient are being performed automatically by the device. Through the introduction of improved circuitry, software and telecommunication capabilities, these devices have become remote medication management systems, with the patient now coming to depend upon the design and operation of these systems to select and deliver medications uncontaminated and in the correct dosage according to a pre-programmed dispensing schedule.

This revolution in patient medication management from pill box (with or without an alarm clock) to remote medication management systems was marked by FDA on October 19, 2007, when the Agency announced in the Federal Register a final rule classifying "Remote Medication Management Systems" as class II (special controls) devices "in order to provide a reasonable assurance of safety and effectiveness of these devices".[8]

d. *FDA Classification and Regulation of Remote Medication Management Systems*

On September 20, 2006, FDA issued an order automatically classifying a remote medication management system manufactured by INRange Systems, Inc. (referred to hereafter as the "***INRange Device***") in class III

> " . . . because [the INRange Device] was not within the type of device which was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device that was subsequently reclassified into class I or class II."[9]

---

[7] See, e.g., Col N et al. The role of medication noncompliance and adverse drug reactions in hospitalizations of the elderly. Arch Intern Med. 1990;150:841-845; Strandberg LR. Drugs as a reason for nursing home admissions. J Am Health Care Assoc. 1984;10:20-23.

[8] 72 FR 59175 (October 19, 2007)

[9] 72 FR 59175 (October 19, 2007)

On September 25, 2006, INRange petitioned FDA to reclassify the INRange Device, recommending that the Device be classified into class II[10]. On June 13, 2007, FDA issued an order to INRange classifying the INRange Device into class II.[11]

By order announced October 17, 2007, FDA announced that it was classifying devices of the generic type represented by the INRange Device into class II (special Controls).[12] At the same time, FDA amended 21 CFR Part 880 by the addition of new Section 880.6315 ("Remote Medication Management System"), and it announced the availability of a guidance document entitled, "Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Remote Medication Management System" (referred to hereafter as the "***Medication Management System Guidance***").[13]

In announcing this regulatory action, FDA identified the following risks to health associated with a Remote Medication Management System to explain the need for Special Controls to provide reasonable assurance of safety and efficacy:

- Improper dosage delivered to patient;
- Cross-contamination of medications;
- Compromised information security;
- Failure of the device;
- Electromagnetic interference; and
- Electrical and mechanical hazards.[14]

FDA further defined a Remote Medication Management System of the type included within the meaning of Section 880.6315 and subject to the Medication Management System Guidance to be:

> " . . . composed of clinical and communications software, a medication delivery unit, and medication packaging[;]"[15]

and to be intended:

> " . . . [1] to store the patient's prescribed medications in a delivery unit, [2] to permit a health care professional to remotely schedule the patient's prescribed medications, [3] to notify the patient when the prescribed medications are due to

---

[10] See, Petition from INRange Systems, Inc., dated September 25, 2006, on display in the FDA Division of Dockets Management.
[11] 72 FR 59175 (October 19, 2007)
[12] Ibid
[13] Ibid
[14] 72 FR 59175 (emphasis added)
[15] 21 CFR §880.6315

> be taken, [4] to release the prescribed medications to a tray of the delivery unit accessible to the patient on the patient's command, and [5] to record a history of the event for the health care professional."[16]

FDA further identified that such a System "is intended for use as an aid to health care professionals in managing therapeutic regimens for patients in the home or clinic."[17]

Significantly, FDA did not find that the general controls of the Act of the type applicable to "daily assist devices" within the scope of 21CFR Section 890.5050, such as Solid Medication Dispensers or Medication Reminders, were sufficient to address the safety issues presented by devices within the generic type of devices it had classified as Remote Medication Management Systems. FDA had identified these risks in announcing its order establishing this classification; it elaborated on these risks in the Medication Management System Guidance as follows[18]:

| **Identified Key Risks to Health** | **Source of Risk and Recommended Measures or Components to Remediate Risk** |
|---|---|
| Improper Dosage Delivered to Patient | "FDA believes that the software used to operate the device presents a "major level of concern" as described in the Software Guidance because there may be potential for a patient to miss necessary medication, or receive an incorrect dose of a drug or the wrong drug, which could lead to serious injury or death, if the device fails because of a software defect."[19] |
| Cross-Contamination of Medications | "Cross-contamination between different medications, either through contact within the medication delivery unit or through medication residues in the medication delivery unit creates a potential for adverse reactions, especially if a medication is no longer used by the patient because an allergy to that medication developed or was discovered."[20] |

The Medication Management System Guidance emphasizes FDA's concern over the ability of the Remote Medication Management System to correctly identify, select and deliver the medication prescribed for the patient. In particular, FDA has observed that

> "[o]ne source of medication error is the inability of the patients to properly identify their medications. The medication delivery unit of the remote medication management system should identify the medication without relying upon the patient to accomplish this task[;]

and

---

[16] Ibid
[17] Ibid
[18] See, "Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Remote Medication Management System" (referred to hereafter as the "Medication Management System Guidance")
[19] Ibid
[20] Ibid

> [b]ecause patients may rely on the device to properly deliver their medications, the electromechanical systems of the medication delivery unit should reliably discharge a medication at the prescribed time and in the prescribed dose."[21]

These risks were identified because the indications for use include the treatment of patients who require detailed medication management in their home or domicile similar to that provided in an acute care environment. The patients relying on the device to properly administer their medications are often without immediate access to the pharmacist instructions (usually located on the prescription label located on the front of the amber bottle). Therefore, the patient relies solely on the device to properly deliver the medications. The risks associated with the device improperly delivering the medications include hospitalization and even death.

[21] See, Medication Management System Guidance, p. 8.

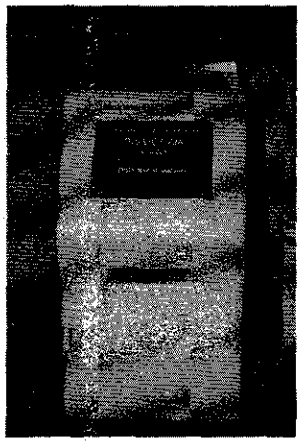
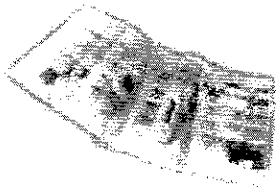
## 2. Products that are Remote Medication Management Systems and are Misbranded and Adulterated Devices

The following products incorporate components and have intended functions and an intended use which establish they are within the generic type of device within the scope of 21 CFR 880.6315 and classified as Remote Medication Management Systems:

a. "*MedAssure Medication Management System*[22]"

-- manufactured by: Concept Medical Technologies, Inc.

The MedAssure Medication Management System (pictured below and see additional product information attached hereto as Exhibit A) consists of the following components:

| | | |
|---|---|---|
|  |  |  |
| Figure #6A: Home Delivery Unit | Figure #6B: Medication Packaging | Figure #6C: Medication Packaging with Bar Coding and Labeling for specific delivery period |

- A home delivery unit pictured in Figure 6A, which dispenses the medications on the patient's command.
- Medication Packaging pictured in Figure 6B & 6C that holds the medications.
- Clinical software (not shown) that is used by the pharmacy to package, label and bar code the medication packages.

[22] Images of the device included in this Petition were obtained from www.conceptmedtech.com; information concerning the device and its functions and intended use that could be obtained from this website are attached to this Petition as Exhibit A; additional information about the device is available at this website.

The base unit is for one user, and is intended to be installed in the patient's home.

As described in the available product information, the medication is loaded into the pill packages at the pharmacy using standard pharmacy loading equipment used in acute care facilities and can hold multiple medications. This type of packaging is normally verified by a nurse prior to delivering to a patient against the patient's most up-to-date medication regimen to insure that no changes have been made since the medication was packaged. The nurse will then make any required adjustments to the package prior to delivering to the patient.

In comparing the components, intended functions and intended use of the MedAssure Medication Management System to the type of generic device within the scope of 21 CFR Section 880.6315, it is clear that this System should be classified as a "Remote Medication Management System", as outlined below:

| **Device** | **Remote Medication Management System (21 CFR §880.6315)** | **"MedAssure" *manufactured by:* Concept Medical Technologies, Inc.[23]** |
|---|---|---|
| **Components:** | [1] clinical and communications software<br>[2] medication delivery unit<br>[3] medication packaging | [1] Clinical software used by the pharmacist to label and bar code the medication packages that are loaded into the machine which utilized the bar code to transfer the information to the Delivery Unit.<br>[2] A Medication Delivery Unit<br>[3] Medication Packaging |
| **Intended Function:** | [1] to store the patient's prescribed medications in a delivery unit,<br>[2] to permit a health care professional to remotely schedule the patient's prescribed medications,<br>[3] to notify the patient when the prescribed medications are due to be taken,<br>[4] to release the prescribed medications to a tray of the delivery unit accessible to the patient on the patient's command, and<br>[5] to record a history of the | [1] Storing the patients prescribed medication in a delivery unit in pre-packaged containers.<br>[2] Enabling the healthcare provider to remotely (from their pharmacy) schedule the patient's medication using the bar code on the package.<br>[3] An audible alarm that notifies the patient when it is time to take their medications.<br>[4] Release the prescribed medications from their strip pack into a tray of the delivery unit on the patient's command.<br>[5] Records the event utilizing the |

[23] Ibid

| | | |
|---|---|---|
| | event for the health care professional. | internet hub or phone line. |
| **Intended Use:** | an aid to health care professionals in managing therapeutic regimens for patients in the home or clinic | an aid to healthcare professions in the control and delivery of prescription drugs to patients in an outpatient setting. |

By components, intended function and intended use, the MedAssure System is clearly a Remote Medication Management System within the meaning of 21 CFR §880.6315. Consequently, in the absence of device and establishment registration and pre-market notification as required under the Act, the MedAssure System is a misbranded device.

b. "*MediSure Medication Dispensing System*"[24]

-- manufactured by: Rapid Patient Monitoring, LLC

The MediSure Medication Dispensing System (pictured below and see additional product information attached hereto as Exhibit B) consists of the following components:

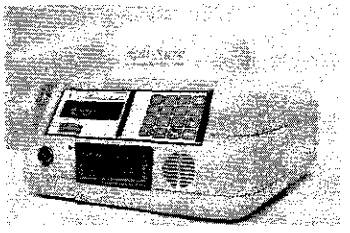


Figure #4A: Home Delivery Unit

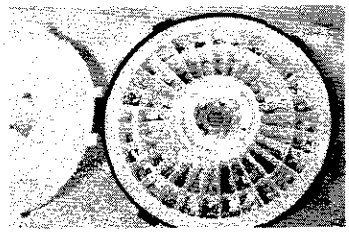


Figure #4B: Medication Cartridge

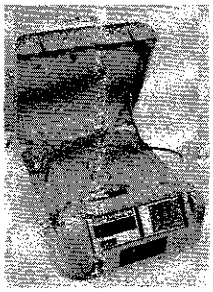


Figure #4C: Home Delivery Unit without the Medication Cartridge

Figure #4D: Home Delivery Unit with the Medication Cartridge Installed

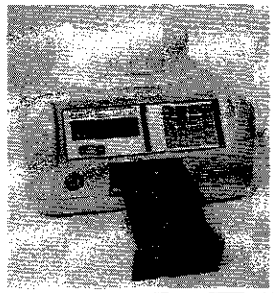


Figure #4E: Home Unit with Medication Delivery drawer Open

[24] Images of the device included in this Petition were obtained from www.rapidpatientmonitoring.com; information concerning the device and its functions and intended use that could be obtained from this website are attached to this Petition as Exhibit B; additional information about the device is available at this website.

1. A clinical software system allows a pharmacist to program a chip contained within the Medication Cartridge (Figure #4B). The chip contains the delivery instructions which are communicated to the Home Delivery Unit when the Medication Cartridge is placed within the Unit (figure #4D).

2. A Medication Cartridge (Figure #4B) or package which is loaded by a Pharmacist in his office with the medications for the patient. The medications are loaded using a fixture into specific compartments which correspond to the programming entered into the chip by the pharmacist.

3. A Home Delivery Unit (Figure #4A). This Unit stays in the home and is opened by the caregiver (Figure #4C) and the Medication Cartridge (Figure #4B) is inserted into the home unit. The computer in the Home Unit communicates with the chip contained within the Medication Cartridge to obtain the delivery instructions programmed by the Pharmacist.

As described in the available product information, to alter a medication dosing schedule, the cartridge is removed from the unit, returned to the pharmacist, who then alters the doses in the cartridge and reprograms the chip contained within the cartridge. The cartridge is then returned to the unit.

When it is time to take a medication the unit provides an audible and visual alert for the patient to take their medications. The medications are then delivered to the patient when the patient depresses the dispense button and the event is communicated back to the pharmacy via an internet connection.

In comparing the components, intended functions and intended use of the MediSure Medication Dispensing System to the type of generic device within the scope of 21 CFR Section 880.6315, it is clear that this System should be classified as a "Remote Medication Management System", as outlined below:

| **Device** | **Remote Medication Management System (21 CFR §880.6315)** | **"MediSure Medication Dispensing System"** ***manufactured by:*** **Rapid Patient Monitoring, LLC** |
|---|---|---|
| **Components:** | [1] clinical and communications software<br>[2] medication delivery unit<br>[3] medication packaging | [1] Clinical software used to program the chip contained within the Medication Cartridge and communications software which transfers this data from the chip to the Delivery Unit in the patient's home or domicile.<br>[2] A Medication Delivery Unit<br>[3] Medication Packaging & Cartridge |

| | | |
|---|---|---|
| **Intended Function:** | [1] to store the patient's prescribed medications in a delivery unit,<br>[2] to permit a health care professional to remotely schedule the patient's prescribed medications,<br>[3] to notify the patient when the prescribed medications are due to be taken,<br>[4] to release the prescribed medications to a tray of the delivery unit accessible to the patient on the patient's command, and<br>[5] to record a history of the event for the health care professional. | [1] Storing the patients prescribed medication in a delivery unit utilizing their cartridges.<br>[2] Enabling the healthcare provider to remotely (from their pharmacy) schedule the patient's medication using a computer chip embedded within their medication cartridge.<br>[3] An audible alarm that notifies the patient when it is time to take their medications.<br>[4] Release the prescribed medications from their cartridge into a tray of the delivery unit on the patient's command.<br>[5] Records the event utilizing the internet hub. |
| **Intended Use:** | an aid to health care professionals in managing therapeutic regimens for patients in the home or clinic | An aid in the control and delivery of prescription drugs to patients in an outpatient setting. |

By components, intended function and intended use, the MediSure System is clearly a Remote Medication Management System within the meaning of 21 CFR §880.6315. Consequently, in the absence of device and establishment registration and pre-market notification as required under the Act, the MediSure System is a misbranded device.

c. *"MedSignals Medication Management System"*[25]

-- manufactured by: MedSignals Corp., a division of LIFETECHniques, Inc.

The MedSignals Medication Management System (pictured below and see additional product information attached hereto as Exhibit C) consists of the following components:

- A home delivery unit pictured in Figure 7, which holds up to 4 different medications in compartments.
- Medication Packaging (not shown) from the pharmacist, which includes standard amber pill bottles typically dispensed by a pharmacy.
- Clinical software (not shown) that is used by the pharmacy to transmit via phone line to the Delivery Unit the updated medication schedules.

[25] Images of the device included in this Petition were obtained from www.medsignals.com; information concerning the device and its functions and intended use that could be obtained from this website are attached to this Petition as Exhibit C; additional information about the device is available at this website.

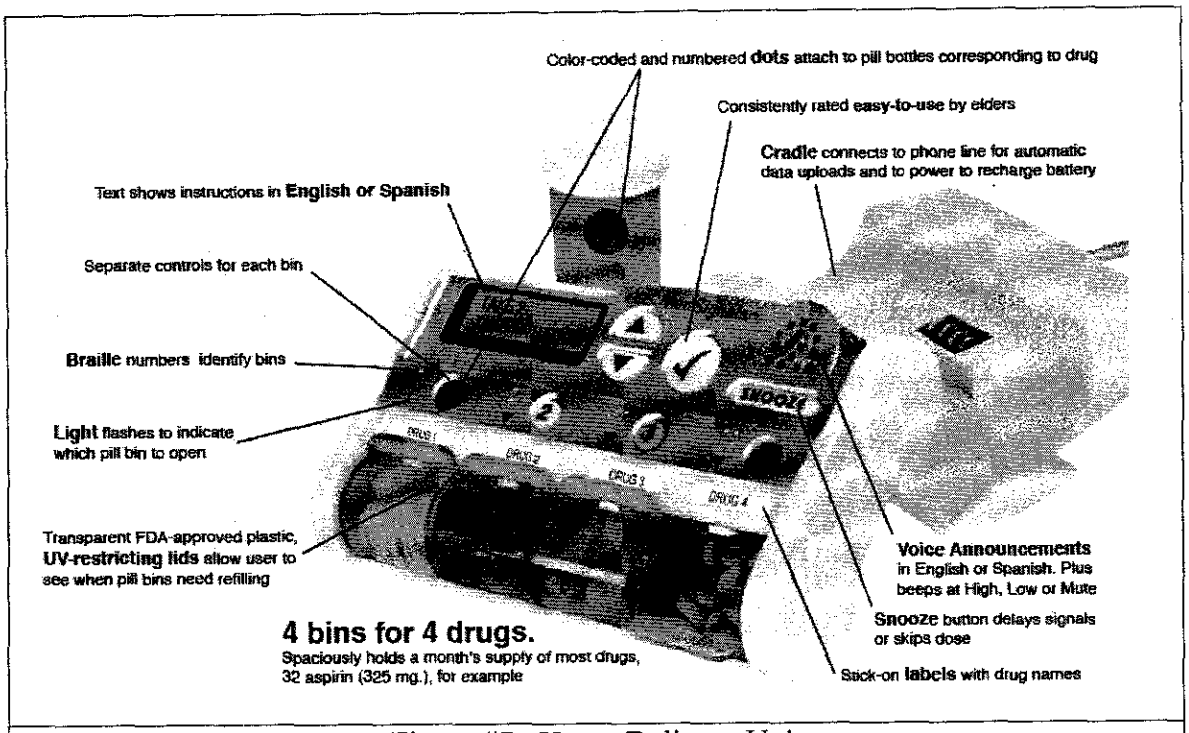



Figure #7: Home Delivery Unit

The medications are loaded into the correct compartments by the pharmacist, and, according to the available product information, the MedSignal Device:

> "holds four drugs in separate, programmable compartments, each with its own associated signals. No more loading pills day-by-day into pillboxes. Program each bin on the device or point-and-click on the web (which automatically downloads programming to the device on next phone connection.) Select optimal times to take the medication, indicate how many to take, and choose optional warnings or instructions applicable to the drug."[26]

The MedSignals Medication Management System is intended to deliver an audible signal when a dose is due to be taken. A flashing LED is intended to signal which drug is to be taken. Other audible and visual signals follow::

- Voice announcements repeat how many pills to take and associated warnings you chose
- The number of beeps match the number of pills to be taken
- The LED flashes the number of pills to take

[26] See, www.medsignals.com

- Text appears on the screen, in English or Spanish, indicating how many to take and what instruction or warning to heed. If the time isn't convenient, press the Snooze button for a 30-minute delay. Or, if you wish to skip the dose, press the Snooze button twice to silence it until the next scheduled dose."[27]

In comparing the components, intended functions and intended use of the MedSignals Medication Management System to the type of generic device within the scope of 21 CFR Section 880.6315, it is clear that this System should be classified as a "Remote Medication Management System", as outlined below:

| **Device** | **Remote Medication Management System (21 CFR §880.6315)** | **"MedSignals Medication Management System"** ***manufactured by:*** **MedSignals Corp., a division of LIFETECHniques, Inc** |
|---|---|---|
| **Components:** | [1] clinical and communications software<br>[2] medication delivery unit<br>[3] medication packaging | [1] Clinical software used by the pharmacist program the remote delivery unit with the updated medication schedules.<br>[2] A Medication Delivery Unit<br>[3] Medication Packaging |
| **Intended Function:** | [1] to store the patient's prescribed medications in a delivery unit,<br>[2] to permit a health care professional to remotely schedule the patient's prescribed medications,<br>[3] to notify the patient when the prescribed medications are due to be taken,<br>[4] to release the prescribed medications to a tray of the delivery unit accessible to the patient on the patient's command, and<br>[5] to record a history of the event for the health care professional. | [1] Storing the patients prescribed medication in a delivery unit in pre-packaged containers.<br>[2] Enabling the healthcare provider to remotely (from their pharmacy) schedule the patient's medication using a phone line or internet.<br>[3] An audible alarm that notifies the patient when it is time to take their medications.<br>[4] Release the prescribed medications on the patient's command.<br>[5] Records the event utilizing the internet hub or phone line. |

[27] Ibid

| | | |
|---|---|---|
| **Intended Use:** | an aid to health care professionals in managing therapeutic regimens for patients in the home or clinic | an aid to healthcare professions in the control and delivery of prescription drugs to patients in an outpatient setting. |

By components, intended function and intended use, the MedSignals System is clearly a Remote Medication Management System within the meaning of 21 CFR §880.6315. Consequently, in the absence of device and establishment registration and pre-market notification as required under the Act, the MedSignals System is a misbranded device.

d. "*PillStation*"[28]

-- manufactured by: SentiCare, Inc.

The PillStation (pictured below and see additional product information attached hereto as Exhibit D) consists of the following components:

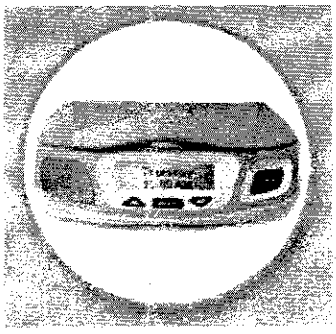


Figure #5A: Home Delivery Unit

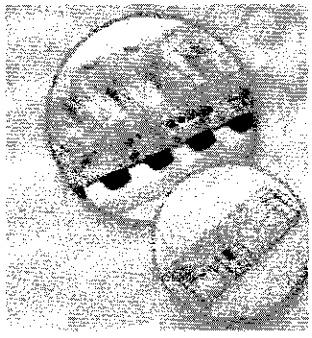


Figure #5B: Medication Cartridge


Figure #5C: Home Delivery Unit showing Medication cartridge and Reminder Display

The PillStation utilizes individual pill compartments for each time period throughout a day. Seven compartments are inserted into the Delivery Unit to make up a week's medications. The patient or other caregiver (not a pharmacy tech or any type of licensed professional) in the home loads the cartridges and utilizing vision technology, the images of each cartridge is electronically transmitted to central service where an "expert" reviews to insure that the compartment has been loaded correctly.

When it is time for the patient to take their medications, the compartment glows and an alarm sounds. The patient removes the medications from the compartment. Then using vision

[28] Images of the device included in this Petition were obtained from www.senticare.com; information concerning the device and its functions and intended use that could be obtained from this website are attached to this Petition as Exhibit D; additional information about the device is available at this website.

technology, the compartment is checked by a central service to make sure that the medications have been taken.

In comparing the components, intended functions and intended use of the PillStation to the type of generic device within the scope of 21 CFR Section 880.6315, it is clear that this device should be classified as a "Remote Medication Management System", as outlined below:

| **Device** | **Remote Medication Management System (21 CFR §880.6315)** | **"Pill Station"** ***manufactured by:*** **SentiCare, Inc.** |
|---|---|---|
| **Components:** | [1] clinical and communications software<br>[2] medication delivery unit<br>[3] medication packaging | [1] Clinical and communications software that transmits images to a central service so they can be analyzed by "experts" by their central service<br>[2] A Medication Delivery Unit<br>[3] Medication Packaging / Cartridge consisting of compartments where the pills are loaded and verified. |
| **Intended Function:** | [1] to store the patient's prescribed medications in a delivery unit,<br>[2] to permit a health care professional to remotely schedule the patient's prescribed medications,<br>[3] to notify the patient when the prescribed medications are due to be taken,<br>[4] to release the prescribed medications to a tray of the delivery unit accessible to the patient on the patient's command, and<br>[5] to record a history of the event for the health care professional. | [1] Storing the patients prescribed medication in a delivery unit inside of compartments.<br>[2] Enabling the healthcare provider to remotely (from their central service station) verify the loading and schedule of the patient's medication using vision technology.<br>[3] An audible alarm that notifies the patient when it is time to take their medications.<br>[4] Release the prescribed medications from their compartment by the patient by lighting the compartment of he pills to be taken.<br>[5] Records the event utilizing the internet hub. |
| **Intended Use:** | an aid to health care professionals in managing therapeutic regimens for patients in the home or clinic | An aid to healthcare professions in the control and delivery of prescription drugs to patients in an outpatient setting. |

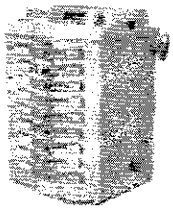
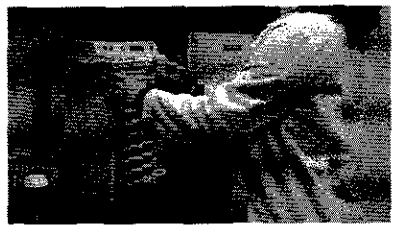
By components, intended function and intended use, the Pill Station is clearly a Remote Medication Management System within the meaning of 21 CFR §880.6315. Consequently, in

the absence of device and establishment registration and pre-market notification as required under the Act, the Pill Station is a misbranded device.

e. *"TabSafe Medication Management System"*[29]

-- manufactured by: TabSafe Medical Services, Inc.

The TabSafe Medication Management System (pictured below and see additional product information attached hereto as Exhibit E) consists of the following components:

| | | |
|---|---|---|
|  |  |  |
| Figure #3A: Home Delivery Unit | Figure #3B: Medication Packaging / Cartridges | Figure #3C: Clinical Software / Chip "Burner" for programming the Cartridge |

TabSafe describes the operation of its Medication Management System as follows:

"The TabSafe system consists of three major components:

1. The base, or "bedside" unit
2. Pill delivery cartridges which are loaded at a pharmacy
3. A coordinating system utilizing the internet as a hub.

The base unit is for one user, and is installed at the bedside (or other convenient location), in the home or in the extended care facility. It holds nine cartridges."

The medication is loaded at the pharmacy into a cartridge instead of a pill bottle, one type of medication per cartridge. Its patented design allows one tablet to be released at a time. . . . A memory chip embedded in each TabSafe cartridge allows the pharmacist to interface and enter each customer's medication information at the same time a label is generated." [30]

The central control system for TabSafe maintains a database of information for the medication supplied to each individual TabSafe Medication Management System – the status of each cartridge (which medication it contains, the quantity remaining, schedule times, and

[29] Images of the device included in this Petition were obtained from www.tabsafe.com; information concerning the device and its functions and intended use that could be obtained from this website are attached to this Petition as Exhibit E; additional information about the device is available at this website.

[30] See, www.tabsafe.com

expiration dates), detailed prescription data, and compliance records. It also coordinates payment and reordering."[31]

In comparing the components, intended functions and intended use of the TabSafe Medication Management System to the type of generic device within the scope of 21 CFR Section 880.6315, it is clear that this System should be classified as a "Remote Medication Management System", as outlined below:

| **Device** | **Remote Medication Management System (21 CFR §880.6315)** | **"TabSafe Medication Management System"** ***manufactured by:*** **TabSafe Medical Services, Inc.**[32] |
|---|---|---|
| **Components:** | [1] clinical and communications software<br>[2] medication delivery unit<br>[3] medication packaging | [1] Clinical software used to program the chip contained within the Medication Cartridge and communications software which transfers this data from the chip to the Delivery Unit in the patient's home or domicile.<br>[2] A Medication Delivery Unit<br>[3] Medication Packaging / Cartridge |
| **Intended Function:** | [1] to store the patient's prescribed medications in a delivery unit,<br>[2] to permit a health care professional to remotely schedule the patient's prescribed medications,<br>[3] to notify the patient when the prescribed medications are due to be taken,<br>[4] to release the prescribed medications to a tray of the delivery unit accessible to the patient on the patient's command, and<br>[5] to record a history of the event for the health care professional."[33] | [1] Storing the patients prescribed medication in a delivery unit utilizing their cartridges.<br>[2] Enabling the healthcare provider to remotely (from their pharmacy) schedule the patient's medication using a computer chip embedded within their medication cartridge.<br>[3] An audible alarm that notifies the patient when it is time to take their medications.<br>[4] Release the prescribed medications from their cartridge into a tray of the delivery unit on the patient's command.<br>[5] Records the event utilizing the internet hub. |

[31] See, www.tabsafe.com
[32] Ibid
[33] Ibid

| | | |
|---|---|---|
| **Intended Use:** | an aid to health care professionals in managing therapeutic regimens for patients in the home or clinic | An aid in the control and delivery of prescription drugs to patients in an outpatient setting. |

By components, intended function and intended use, the TabSafe System is clearly a Remote Medication Management System within the meaning of 21 CFR §880.6315. Consequently, in the absence of device and establishment registration and pre-market notification as required under the Act, the TabSafe System is a misbranded device.

### 3. Medication Management Devices

Medication management devices have proliferated over the past several years, as manufacturers have integrated software and mechanical controls to take over the sorting, selection and dispensing functions historically performed manually by the patient. All of them are trying to address a growing need in the market for improved adherence to prescribed medication regimens. However, by relieving the patient of the responsibility of correctly selecting and dispensing the correct medication in the correct dosage at the prescribed time, they increase the risk of harm to the patient that may result from malfunctions or errors resulting in the device selecting and dispensing the wrong medication at the wrong time.

Many of these new devices are designed for patient self-management. However, they require a person (licensed or non-licensed) to program the device so that it selects the proper medication at the proper time. The intended use and functions of the device are identical to Remote Medication Management Systems as defined by 21 CFR 880.6315, with the exception that these devices are not programmed by a licensed caregiver (such as a Pharmacist). As a result, though, these medication management devices may provide a greater risk to patient safety than Remote Medication Management Systems which are subject to greater caregiver interaction. Significantly, FDA has advised with respect to the design of Remote Medication Management Systems that:

> "We recommend that you limit patient control of the device. The device and its control software should be designed so that none of the interactions between the device and the patient involve the patient entering any information used in the management, scheduling, or identification of the medication."[34]

a. *Examples of Medication Management Devices*

"*Dispense-A-Pill*"[35]

-- manufactured by: HealthOneMed, Inc.;

"*MD.2*"[36]

-- manufactured by: Philips Lifeline

Two such medication management devices are the Dispense-a-Pill and MD.2 (pictured below and see additional product information attached hereto as Exhibit F and Exhibit G,

---

[34] See, Medication Management System Guidance, p. 10.

[35] Images of the device included in this Petition were obtained from www.healthonemed.com; information concerning the device and its functions and intended use that could be obtained from this website are attached to this Petition as Exhibit F; additional information about the device is available at this website.

[36] Images of the device included in this Petition were obtained from www.epill.com; information concerning the device and its functions and intended use that could be obtained from this website are attached to this Petition as Exhibit G; additional information about the device is available at this website.

respectively). Neither of the medication management devices referenced in this Section 3 has been registered with the FDA,

Figure #7a:
Dispense-a-Pill

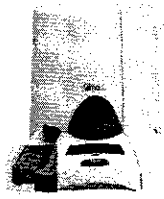


Figure #7b:
MD.2

The Dispense-a-Pill device allows a patient or caregiver to load the pills from a prescription bottle into a compartment contained within the device. The device, like the MD.2 device, is programmed by the patient or caregiver to signal and then to dispense the correct medication(s) at the prescribed time. When it is time to take their medications, an alarm signals the patient and the dispenser automatically selects the proper pills from the internal compartments and delivers them to the patient.[37]

The MD.2 device requires that the patient remove their medications from the labeled bottles and load individual cups into the Delivery Unit. The patient programs the Delivery Unit utilizing the controls on the front of the machine. At each dosing period, an alarm signals the patient and the next cup is rotated to the delivery point and delivered to the patient. A record of this event is then transmitted to a central database where it can be used by a licensed professional to monitor the patient's medication adherence.[38]

While these devices do not provide direct pharmacist / clinician control of the delivery of the patient's medications, they do present the same risks or greater to the patient as Remote Medication Management Systems, including:

**Software.** All of these devices have imbedded computer chips containing software and firmware. A software error can result in the wrong medications being delivered without the patient's knowledge.

**Cross Contamination of Medications.** If the patient has an allergic reaction to one medication, consideration must be given as to how the cartridges / containers holding the medication will be cleaned prior to using them for another medication.

**Patient Programming.** One of the key requirements for Remote Medication Management Systems is usability testing results. Medication management devices require the patient or a non-professional to program the delivery of medications. Therefore, the interface

[37] See, www.healthonemed.com
[38] See, www.epill.com

with the patient for loading and scheduling medication creates a significant potential risk of harm.

**Data Integrity and Security.** These devices all connect to phone lines or other means of communications in order to provide healthcare professionals with information regarding the delivery of medications. This data is considered medical data and is as critical to a physician's decision making as home cardiovascular monitoring data which is considered a Class II Medical Device regulated under 21 C.F.R. § 870.2910. Validation methods and procedures should be required on all devices that perform such functions in order to insure that they are protecting their patient's HIPAA rights and insuring that the data generated is accurate. Furthermore, without proper controls on the loading of the medications and the integrity of the loading and scheduling of the medications in the Delivery Unit, the information, which may be used to make a medical decision, provided to the healthcare professional may be highly inaccurate.

**Patient Reliance on the Device.** Patients relying on these devices are dependent upon their safe operation. Once the medications are loaded into the device, the prescription instruction label is lost to the patient. They are totally dependent upon the device delivering the correct pill at the correct time. Many of these devices will be used by the elderly or patients with cognitive impairments. Should an incorrect dose be delivered (such as with anti-coagulation therapy), the resulting harm to the patient could be significant.

Medication management devices that select and deliver from an array of medications contained within the device should be classified as class II devices and should conform to the general controls of the Act, including the establishment registration and device listing requirements described in 21 CFR §807 Subpart B and the premarket notification requirements described in 21 CFR §807 Subpart E. These devices are clearly more than mere medication dispensers or medication reminders. They are automated systems that identify, select and deliver the proper medication to the patient based on programming inputs supplied by the patient or a caregiver.

## C. Conclusion

Medication management devices are starting to become more common in order to address the medication non-adherence and medication mismanagement problems that occur with out-patient treatment. However, with the exception of the INRange Device, none of the medication management devices presently marketed in the United States appear to have been submitted to FDA for pre-market review, as is presently required for devices of the generic type within the classification of "Remote Medication Management Systems" subject to 21 CFR Section 880.6315. If action is not taken by FDA to require manufacturers of such devices to conform to the general controls of the Act, including the establishment registration and device listing requirements described in 21 CFR §807 Subpart B and the premarket notification requirements described in 21 CFR §807 Subpart E, as required under 21 CFR Section 880.6315, a potential major and growing risk to patient health will remain unaddressed.

The following products are unapproved and misbranded devices, as they include the components and have the same intended functions and intended use as generic devices of the type classified as "Remote Medication Management Systems" and subject to requirements for establishment registration, device listing and premarket notification as set forth in 21 CFR Section 880.6315:

a. "*MedAssure Medication Dispensing System*"

-- manufactured by: Concept Medical Technologies, Inc.

P.O. Box 430098
Birmingham, AL 35243
Telephone: 205-970-1100
Website: www.conceptmedtech.com

b. "*MediSure Medication Dispensing System*"

-- manufactured by: Rapid Patient Monitoring, LLC

1600 South 28th Street
Philadelphia, PA
Telephone: 215-336-1766
Website: www.rapidpatientmonitoring.com

c. "*MedSignals Medication Management System*"

-- manufactured by: MedSignals Corp., a division of
LIFETECHniques, Inc.

San Antonio, TX
Telephone: 210-222-2067
Website: www.medsignals.com

d. "*PillStation*"

-- manufactured by: SentiCare, Inc.

132 Turnpike Road
Southborough, MA 01772
Telephone: 509-
Website: www.senticare.com

e. "*TabSafe Medication Management System*"

-- manufactured by: TabSafe Medical Services, Inc.

1050 Northfield Court - Suite 100
Roswell, Georgia 30076
Telephone: 678-990-8450
Website: www.tabsafe.com

As such, the potential risks to patient safety resulting from these devices require that immediate action be taken to require these devices conform to the general controls of the Act, including the establishment registration and device listing requirements described in 21 CFR §807 Subpart B and the premarket notification requirements described in 21 CFR §807 Subpart E.

The following medication management devices are unapproved and misbranded devices, as their indication for use and intended use present specific risks to patient health of the type identified by FDA in establishing the special controls necessary to provide reasonable assurance of safety and efficacy for generic devices of the type classified as "Remote Medication Management Systems" as set forth in 21 CFR Section 880.6315:

a. "*Dispense-A-Pill*"

-- manufactured by: HealthOneMed, Inc.;

1550 Pond Road, Suite 102
Allentown, PA 18104
Telephone: 877-810-2888
Website: www.healthonemed.com

b. "*MD.2*"

-- manufactured by: Philips Lifeline

111 Lawrence Street
Framingham, MA 01702
Telephone: 508-988-1000
Website: www. lifelinesys.com
Product website: www.epill.com/lifelinemd2

Furthermore, all medication management devices currently in commercial distribution in the United States should be recalled until FDA can determine that these devices conform to the general controls of the Act, including the establishment registration and device listing requirements described in 21 CFR §807 Subpart B and the premarket notification requirements described in 21 CFR §807 Subpart E.

## D. Environmental Impact

The action requested is subject to a categorical exemption from environmental assessment under 21 C.F.R. § 25.34.

## E. Economic Impact

Pursuant to 21 C.F.R. § 10.30, Petitioner will provide data concerning the economic impact of the action requested should such information be requested by the FDA.

**F. List of Exhibits**

1. Exhibit A – Product information for "*MedAssure Medication Dispensing System*" from www.conceptmedtech.com (last visited June 17, 2009)

2. Exhibit B – Product information for "*MediSure Medication Dispensing System*" from www.rapidpatientmonitoring.com (last visited June 17, 2009)

3. Exhibit C – Product information for "*MedSignals Medication Management System*" from www.medsignals.com (last visited June 17, 2009)

4. Exhibit D – Product information for "*PillStation*" from www.senticare.com (last visited June 17, 2009)

5. Exhibit E – Product information for "*TabSafe Medication Management System*" from www.tabsafe.com (last visited June 17, 2009)

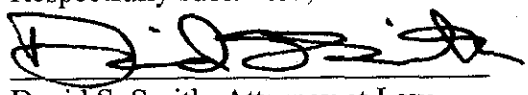
6. Exhibit F – Product information for "*Dispense-A-Pill*" from www.healthonemed.com (last visited June 17, 2009)

7. Exhibit G – Product information for "*MD.2*" from www.epill.com (last visited June 17, 2009)

## G. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this Petition includes all information and views on which this Petition relies, and that it includes representative data and information known to the Petitioner which are unfavorable to the Petition.

Respectfully submitted,



David S. Smith, Attorney at Law
Pepper Hamilton LLP
500 Grant Street - 50th Floor
Pittsburgh, PA 15219
412.454.5862 - Direct
412.291.1951 - Fax
smithds@pepperlaw.com

From: Origin ID: BTPA (412) 454-5000
*David S.Smith*
PEPPER HAMILTON
500 Grant St.
FLOOR 49
**PITTSBURGH, PA 15219**

FedEx Express

J08200906152023

Ship Date: 18JUN09
ActWgt: 1.0 LB
CAD: 1659904/INET9060
Account#: S *********

Delivery Address Bar Code

SHIP TO: (412) 454-5013 **BILL SENDER**
**Division of Dockets Management**
**Food and Drug Administration**
**5630 FISHERS LN RM 1061**
**(HFA- 305)**
**ROCKVILLE, MD 20857**

Ref # 130815 / 2 / 62691
Invoice #
PO #
Dept #

TRK# 0201 7976 9456 2791

**FRI - 19JUN**
**PRIORITY OVERNIGI**

**XC OBTA**

20857
**MD-US**
**IAD**

**After printing this label:**
1. Use the 'Print' button on this page to print your label to your laser or inkjet printer.
2. Fold the printed page along the horizontal line.
3. Place label in shipping pouch and affix it to your shipment so that the barcode portion of the label can be read and scanned.

**Warning**: Use only the printed original label for shipping. Using a photocopy of this label for shipping purposes is fraudulent and co result in additional billing charges, along with the cancellation of your FedEx account number.
Use of this system constitutes your agreement to the service conditions in the current FedEx *Service Guide, available on fedex.com.*FedEx will nc responsible for any claim in excess of $100 per package, whether the result of loss, damage, delay, non-delivery,misdelivery,or misinformation, ul you declare a higher value, pay an additional charge, document your actual loss and file a timely claim.Limitations found in the current FedEx Ser Guide apply. Your right to recover from FedEx for any loss, including intrinsic valueof the package, loss of sales, income interest, profit, attorney's costs, and other forms of damage whether direct, incidental,consequential, or special is limited to the greater of $100 or the authorized declared v Recovery cannot exceed actual documented loss.Maximum for items of extraordinary value is $500, e.g. jewelry, precious metals, negotiable instruments and other items listed in our ServiceGuide. Written claims must be filed within strict time limits, see current FedEx *Service Guide.*

Exhibits A thru G